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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/099,864

03/13/2002

John M. Barker

P02467US1

4471

65008 7590 01/31/2008
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

01/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/099,864

Applicant(s)

BARKER ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,6-8,10-17,19,25-31,61,62,64,65,68-71,73-77 and 79 is/are allowed.
- 6) ☒ Claim(s) 54-55, 57-60, 80-84 and 86-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,6-8,10-17,19,25-31,54,55,57-62,64,65,68-71,73-77,79-84 and 86-89.

DETAILED ACTION

Response to Amendment

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/13/2007 has been entered.

Examiner acknowledges the RCE filed 12/13/2007 in which claims 54 and 80 were amended. Currently claims 1-2, 4, 6-8, 10-17, 19, 25-31, 54-55, 57-62, 64-65, 68-71, 73-77, 79-84 and 86-89 are pending for examination in this application.

Examiner acknowledges the amended abstract to comply with the 150 word maximum.

Claim Objections

Claim 54 and 57 are objected to because of the following informalities: Applicant claims a "pre-filled container" but then references a "container", this second container lacks antecedent basis; Examiner suggests referencing all containers as "pre-filled". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 54-55, 57-60, 80-84 and 86-89 are rejected under 35 U.S.C 103(a) as being unpatentable over O'Neil et al. (USPN5,637,087) in view of Romano et al. (USPN5,795,336). O'Neil et al. discloses a pre-filled, two constituent syringe.

Regarding claims 54-55, 57-60, 80-84 and 86-89, O'Neil et al. discloses a medical device cooperable (Figures 1-3) with a pre-filled container of medicinal fluid (26) comprising: a housing cooperable (12) with a needle assembly; a socket (near 30) for receiving the container; a pressurizing element (40, 46) with piston (42) external to the container and within the housing to provide positive fluid pressure within the container when the container is disposed in the socket (near 30); an empty chamber (16) in the housing for receiving the medicinal fluid from the container, wherein the chamber is configured to receive substantially all of the medicinal fluid ; and a transfer seal (30) disposed between the chamber and the pressurizing element, the transfer seal comprising a conduit (32) for providing a fluid path between the chamber with a

pierceable seal (surfaces of 26, 22) and the container when the container is disposed in the socket (Figures 1-4, cols 1-2).

O'Neil et al. meets the claim limitations as described above except for the retractable needle assembly with stop mechanism.

However, Romano et al. teaches an automatic needle protector assembly.

Regarding claims 54-55, 57-60, 80-84 and 86-89, Romano et al. teaches a needle assembly (Figure 1) having a retractable injection needle (11) to be used with a syringe assembly (81) (Figure 7) with a surface (end of 50) cooperable with the needle assembly and adapted to activate retraction of the needle after use (Figures 8-12).

At the time of the invention, it would have been obvious to use the protective needle device of Romano et al. with the system of O'Neil et al. in order to aid in needle stick protective and prevention of disease transfer. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Romano et al. (cols 1-2).

Allowable Subject Matter

Claim 1-2, 4, 6-8, 10-17, 19, 25-31, 61-62, 64-65, 68-71, 73-77 and 79 allowed over the prior art of record.

Response to Arguments

Applicant's arguments with respect to claims 54-55, 57-60, 80-84 and 86-89 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

1/29/08



CHRISTOPHER D. KOHARSKI
EXAMINER
571-272-7230



Christopher D. Koharski
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